DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on December 10th, 2008. Claims 1, 3, 5-9, 12, 13, 16, 18-22, 26, and 28 are pending. Claims 2, 4, 10, 11, 14, 15, 17, 23, 24, and 27 have been cancelled. Claim 25 is allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, and 5-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a liquid capture material which forms a salt or complex with said matrix ion species, does not reasonably provide enablement for a material (i.e. solid, liquid, or gas) which forms a salt or complex with said matrix ion species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. Applicant's specification, as seen from paragraphs [0073,0074, 0077, 0078] describe that in the case of forming a complex or salt with the matrix ion species, the capture material is in liquid form. Whereas, paragraphs [0077&0078] describe a case where the material is in the form of particles,

solid material, such a case is directed toward a precipitation and not forming a salt or complex with the matrix ion species.

Claims 12, 13, 16, 18-22, 26, and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a liquid sample stream and detecting at least one analyte ion species, in which detecting the at least one analyte ion speces in the sample stream comes with the constitution of a flow-through treatment channel provided with an inlet and first and second outlets, does not reasonably provide enablement for a method for treating a liquid sample stream and detecting at least one analyte ion species in which the treatment channel has an inlet and a single outlet, wherein the analyte ion species is detected in the sample stream. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. Applicant's specification describes detecting in the sample stream and not the carrier stream, in which two outlets are utilized in the treatment channel (paragraphs [0033, 0121-0124] of Applicant's pre-grant publication US 20055/0202563, figure 8a).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, and 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. Claims 1, 3, and 5-9 now recite an inlet and first and second outlets to the treatment channel. Instances through claims 1, 3, and 5-9 which refer to only the outlet of the treatment channel are unclearly recited as the treatment channel is now recited to have first and second outlets. Correction is required.

Claims 1, 3, and 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the detector is structurally related within the device as currently recited. Applicant's amendment recites a fluid conduit located between the treatment channel first outlet, but not the treatment channel second outlet, and the detector, but does not structurally relate the detector within the device. Does Applicant intend to recite that the detector is in fluid communication with the treatment channel first outlet, so as to coincide with the recitation provided with respect to the fluid conduit? Further, it is unclear what is meant by the amended recitation, "…said sample stream flowing through said first conduit." This recitation is unclear, and further appears to be drawn to an active step recited within an apparatus claim, wherein such a step is not given patentable weight in the apparatus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager (5,971,158).

Yager discloses an absorption-enhanced differential extraction device for use in affinity chromatography. Yager discloses a device and method for extracting desired particle from a sample stream containing the desired particles. Yager discloses that the device has a sample stream inlet, an extraction stream inlet, and an extraction channel (treatment channel) in fluid communication with the sample stream inlet and extraction stream inlet. Yager discloses that the extraction channel is for receiving a sample stream (such as those listed in lines 1-17, col. 8) in adjacent laminar flow with an extraction stream (comprised of an organic solvent, see lines 17-29, col. 7), wherein the extraction channel is provided with a sequestering material (matrix ion species capture material) to capture desired particles (particles defined to include ions, see lines 19-26, col. 6). Yager further discloses that a bi-product stream outlet in fluid communication with the extraction channel receives a by-product stream comprising at least a portion of the sample stream from which desired particles have been extracted (concentration lower at the outlet than at the inlet). A product outlet in fluid communication with the extraction channel receives a product, which has the sequestering material and at least a portion of the desired particles (abstract). Yager discloses that the sequestering material can be present in the extraction steam prior to the extraction stream's being introduced into the extraction channel, or the sequestering material can be added to the extraction stream by suspending or dissolving the sequestering material in a liquid which is introduced into the extraction stream (lines 40-46, col. 4). Yager also discloses

that the sequestering material provides for increased diffusion of the desired particles (lines 47-52, col. 5). Yager also discloses that the sample and extraction streams are kept in contact in the extraction channel for a period of time sufficient to allow at least an analyzable quantity, and even small amounts of analytes present may be detected by spectroscopic and other means (line 53, col. 9 – line 5, col. 10). Yager further discloses that the invention may be utilized as a sample pretreatment system for an analytical system including sensing means for detecting desired particles in the product and by-product streams. Yager discloses separating the sample stream from the carrier liquid stream exiting the treatment channel prior to detection within the product stream 13 (cols. 13&14, fig. 3). Yager discloses detection means include optical means such as spectroscopic equipment, and means for detecting fluorescence, chemical indicators, and also any magnetic resonance equipment or other means known to detect the presence of analyte particles such as ions (lines 36-57, col. 11). Yager further discloses various embodiments of extraction devices in columns 13-15.

Yager does not disclose a detector in the device for detecting the at least one analyte ion species in the sample stream.

Yager teaches providing a sequestering material so as to bind the analyte ion species to an extraction channel so as to detect the analyte ion species therein. Yager further discloses two outlets to the treatment channel. Thereby, it would have been obvious to provide a detector at both outlets to the device of Yager so as to provide a complete observation of all the material leaving the device. This would have been obvious as one would want to analyze the other outlet (sample stream outlet) for the

analyte ion species so as to observe if the sequestering material was working properly for the analyte of interest, thus providing results which have a higher degree of quality assurance.

Claims 1, 3, and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocklin (4,751,189) in view of Yager.

Rocklin discloses a method of ion chromatography. Rocklin discloses that the system is useful for determining a large number of ionic species, such as anions and cations. Rocklin discloses that a suitable sample includes surface waters, chemical wastes, body fluids, and beverages such as fruits and wines and drinking water. Rocklin discloses that the term ionic species includes species in ionic form and components of molecules, which are ionizable under the conditions of the system (lines 53-62, col. 2). Rocklin shows in figure 1 an eluent reservoir 14 and sample 13 injected to a chromatographic separation means, such as a chromatographic column 10 which is packed with a separation medium, such as an ion-exchange resin. Rocklin discloses that arranged in series with the column 10 is a suppressor means 11 serving to suppress the conductivity of the effluent from column 10 but not the conductivity of the separated ions (lines 13-34, col. 3, fig. 1). The effluent from suppressor means 11 is directed to a detector in the form of a conductivity cell 12 through conduit 24 (fluid conduit as claimed) for detecting all of the resolved ionic species (lines 35-54, col. 3). Rocklin discloses that in one embodiment of the suppressor device 17, effluent from the chromatographic column is directed through the effluent flow channel 26 (treatment

channel; outlets at effluent end and at waste channel 22) bounded on both sides by ion-exchange membranes 27, and the ion-exchange membranes are preferably permeable to ions of the same charge as the exchangeable ions of the membrane and resists permeation of ions of opposite charge. Rocklin further discloses that the membranes are simultaneously contacted on their outersides with the regenerate flowing in the opposite direction through the regenerate flow channels 28. Ions extracted from the effluent (sample stream) at the active ion-exchange sites of the membranes are diffused through the membranes and are exchanged with ions of the regenerate (carrier stream), and thus diffused ultimately into the regenerate (lines 8- 44, col. 4). Rocklin discloses that a suitable regenerate solution is dilute sulphuric acid (lines 28-37, col. 5).

Rocklin does not disclose a matrix ion species capture material included in the carrier stream.

Yager has been discussed above.

It would have been obvious to modify Rocklin to include a sequestering material in the carrier stream such as taught by Yager in order to provide a means for increasing diffusion of the desired particles while no longer requiring the added elements of the ion exchange membranes in the flow channels.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yager in view of Cais et al. (4,510,058), hereafter Cais.

Yager has been discussed above.

Yager discloses the use of various solvents for the carrier liquid. Yager also discloses various sample streams for use within the device that are immiscible with the various organic solvents disclosed. Yager does not specifically disclose any specific pairs of solvent and sample stream which are immiscible with each other.

Cais discloses a column chromatography technique. Cais discloses that the dynamic chromatography can be utilized also in liquid ion exchangers, such as in liquid-liquid extraction systems. Cais discloses that liquid-liquid extraction operates in a manner by interchange of ions at the interface between an aqueous solution and an immiscible solvent with negligible distribution of the extractant to the aqueous phase (lines 3-10, col. 8).

It would have been obvious for Yager to choose a given solvent and a sample stream that is immiscible with the given solvent such as taught by Cais in order to provide a liquid-liquid extraction system for interchange of ions in which there is negligible distribution of the extractant to the aqueous phase.

Allowable Subject Matter

Claim 25 is allowed.

The following is an examiner's statement of reasons for allowance: The prior art of record, namely Yager (5,971,158) and Rocklin (4,751,189), do not teach or fairly suggest a method for treating a liquid sample stream including at least one analyte ion species and matrix ion species as recited in claim 25, which includes that the capture

material binds the matrix ion species by forming a salt or complex. Yager and Rocklin in view of Yager disclose the binding of the analyte ion species to the capture material to form a complex in the product stream for detection and do not suggest binding the matrix ion species (i.e. the undesired particles) to the capture material. Further, Seidel et al. (6,153,393) discloses providing a reagent to eliminate interference by nonspecific interactions in immunoassays to avoid false-positive detection reactions. Seidel discloses a capture material for binding and forming a complex with the analyte ion species in order to reduce interference and false detection results, and does not teach or fairly suggest eliminating such interference by binding the matrix ion species (i.e. the undesired particles for detection) to the reagent (capture material).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

Applicant's arguments with respect to claims 1 and 5-9 as being anticipated under 35 USC 102(b) by Yager have been considered but are moot in view of the new ground(s) of rejection. In view of Applicant's amendments to the claims, the rejection under 35 USC 102(b) has been removed and claims 1 and 5-9 stand rejected under 35 USC 103(a) over Yager, as discussed above.

With respect to the device of claim 1, Applicant argues that Yager does not disclose a detector for the sample stream. Examiner argues that whereas Yager does not disclose a detector for the sample stream, such a modification is seen as obvious for the reasons discussed above.

As claim 1 does not have any such deficiencies, dependent claims 5-9 are said to be properly rejected over Yager, as discussed above.

Rejection of claims 12-21, 23, 24, and 28 under 35 USC 102(b) as being anticipated by Yager (or, with respect to claim 21, obvious over Yager in view of Cais) has been removed in view of Applicant's amendments to the claims.

Applicant's arguments with respect to claims 1, 3, and 5-9 rejected under 35 USC 103(a) over Rocklin in view of Yager have been considered but are moot in view of the new ground(s) of rejection. In view of Applicant's amendments to the claims, the rejection under 35 USC 103(a) has been removed and claims 1, 3, and 5-9 are now rejected under 35 USC 103(a) as discussed above.

With respect to the device of claim 1, Applicant argues that Rocklin is not only missing a matrix ion species capture material in the carrier stream. Applicant argues that Rocklin discloses the use of ion exchange membranes in a suppressor. By this, it is unclear what additional elements the disclosure of Rocklin is missing from the present claims. Examiner argues that, as presented above, it would have been obvious to modify Rocklin to include a sequestering material in the carrier stream such as taught

by Yager in order to provide a means for increasing diffusion of the desired particles while no longer requiring the added elements of the ion exchange membranes in the flow channels. This is seen as an obvious alternative for the same purpose of isolating the ions of interest for detection.

As claim 1 does not have any such deficiencies, dependent claims 3 and 5-9 are said to be properly rejected over Rocklin in view of Yager, as discussed above.

Rejection of claims 12, 16, 18-22, 26, and 28 under 35 USC 103(a) as being obvious over Rocklin in view of Yager has been removed in view of Applicant's amendments to the claims.

Claims 1, 3, and 5-9 are now rejected under both 35 USC 112, 1st paragraph and 35 USC 112, 2nd paragraph, as discussed above, in view of Applicant's amendments to the claims.

Claims 12, 13, 16, 18-22, 26, and 28 are now rejected under 35 USC 112, 1st paragraph, as discussed above, in view of Applicant's amendments to the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/
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